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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/561,122

02/02/2006

Michael Klingeberg

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OSTROLENK FABER GERB & SOFFEN
1180 AVENUE OF THE AMERICAS
NEW YORK, NY 100368403

EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT

PAPER NUMBER

1623

MAIL DATE

DELIVERY MODE

06/11/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,122	Applicant(s) KLINGEBERG ET AL.	
	Examiner TRAVISS C. MCINTOSH III	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/14/05, 6/7/07, 4/3/08, 6/9/08, 11/4/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

The documents lined through in the IDS's filed 12/14/2005 and 4/3/2008 were lined through as they are listed incompletely on the IDS form. See § 1.98 "Content of information disclosure statement":

Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 76 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 76 provides that the infectious disease of claim 75 is selected from the group consisting of bacterial intestinal infections and diarrheas. However, diarrhea is not seen to be an infectious disease, as such, this recitation is confusing.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 74 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants are not enabled for treating intestinal cancer.

The claimed invention relates to a method for the treatment of intestinal cancer. The relative skill of those in the art is generally that of a PHD candidate or PHD. USP 5,919,816 represents a standard publication in the art and as such is directed to those having ordinary skill in the art. USP 5,919,816 demonstrates the unpredictability of the claimed subject matter. For example see column 1 , lines 35-65, which teaches that the mechanisms by which anticancer drugs work are not well understood. Given this, the skilled artisan will appreciate that results obtained with a given agent for a particular cancer type (i.e. pancreatic cancer), which would be treated via different mechanisms, in an a priori manner. See also the various case law which supports the assertion that cancer treatment across tissue types is unpredictable, e.g. *Ex parte Timmis*, 123 USPQ 581 (1959) and *In re Buttinn*, 163 USPQ 689 (1969). Given the above facts,

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it is clear that the art to which the instant invention relates involves a relatively high degree of unpredictability.

The breadth of the claims

Claim 74 is drawn to treating intestinal cancer.

The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for treating any types of cancer.

The quantity of experimentation necessary

Applicant fails to provide guidance and information sufficient to allow the skilled artisan to ascertain cancer can reasonably be treated with the claimed compounds without resorting to undue experimentation. Treating would have to be conducted on various intestinal cancer types, with no expectation of success for the treatment of any particular cancer. Prebiotics may have established utility in the art in reducing the risk of obtaining cancer, but there is nothing in the art showing that a subject having cancer would be effectively treated with a prebiotic containing composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 47-53, 60-72, and 77 are rejected under 35 U.S.C. 102(b) as being anticipated by Tangsen et al. (The Natural New-Type Sweetening Agent”, from 6/7/2007 IDS).

Tangsen et al. disclose palatinitol ingestion which shows that the absorption rate is low, most metabolites are utilized and fermented by microorganisms in the intestines to produce small molecular organic acids, CH₄, CO₂, H₂, and so on, which are discharged outside the body. Thus, Tangsen discloses administering palatinitol which acts as prebiotic. Prebiotics are known to be selectively fermented ingredients that allow specific changes, both in composition and/or activity in the gastrointestinal microflora that confers benefits upon the hosts well-being and health. Tangsen notes that palatinitol can be used to treat diseases such as hepatic coma and so on (see top of page 4). Tangsen states that there are palatinitol-containing foods on the market, such as candies, chocolates, kernel soft candies, chewing gums, ice creams, jellies, jams, etc. It is noted that the mixture applicants are seen to be using, as evidenced by claim 53, is isomalt. Isomalt is the same product as palatinitol (see section 1.2 on page 2 which provides palatinitol is a mixture of 1,6-GPS and 1,1-GPM). As such, the methods of administering the same products to the same population would have necessarily produced the same results. Thus, the step of administering the compositions would have performed functions such as: restoring intestinal flora; maintaining a healthy intestinal epithelium; supporting intestinal health; reducing toxic and harmful intestinal contents; reducing oxidative stress; and strengthening the immune system. The examiner would like to note that Tangsen et al.'s methodological step of administering their isomalt composition DNA would have inherently performed the method as instantly claimed. It is noted that if Tangsen et al., having taken the manipulative steps described therein, had attempted to measure for the results as described in the instant application, Tangsen would have uncovered those

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results, as they are directly correlative to the method as practiced therein. Applicant's discovery of differing effects of a prior art method does not give the discoverer a right to exclude others from practicing the prior arts method of using isomalt containing products as claimed, as the prior arts method would have inherently performed the method as instantly claimed. See **Ex Parte Novitski**, 26 USPQ 2d (BNA) 1389. A hypothetical example clarifies this principle.

Humans lit fires for thousands of years before realizing that oxygen is necessary to create and maintain a flame. The first person to discover the necessity of oxygen certainly could not have obtained a valid patent claim for "a method of making a fire by lighting a flame in the presence of oxygen." Even if prior art on lighting fires did not disclose the importance of oxygen and one of ordinary skill in the art did not know about the importance of oxygen, understanding this law of nature would not give the discoverer a right to exclude others from practicing the prior art of making fires. **EMI v. Cypress Semiconductor**, 2001 US Fed. Cir. Ct. of App. As such, Tangsen teaches the instantly claimed mixture has prebiotic effects and the steps of administration would necessarily produce the results instantly claimed.

Claims 47-56, 60-65, 67-73, and 75-77 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,139,864.

The '964 patent discloses isomalt compositions which have antibacterial effects. The compositions are taught to be combined with additional saccharides (see column 2, lines 25-37); included in medicaments and foods (see column 2, lines 38-65); and combined with various active agents (see column 4, lines 53-65). As such, the same compositions (isomalt containing

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compositions) are taught to be used with the same populations, thus would necessarily produce the same results.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-73 and 75-77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tangsen et al. (The Natural New-Type Sweetening Agent”, from 6/7/2007 IDS) as applied to claims 47-53, 60-72, and 77 above, and further in view of EP0904784.

The claims of the instant application are drawn to methods of forming consumable products with a mixture of 1,6-GPS and 1,1-GPM to serve at least one of a prebiotic function and a fermentable substrate. Dependent claims provide the mixture is isomalt; additional dietary agents are added thereto; the mixture is in the form of food/feed; and used as a medicament. Also claimed are methods of treating bowel disorders; restoring intestinal flora; maintaining a healthy intestinal epithelium; supporting intestinal health; reducing toxic and harmful intestinal contents; reducing oxidative stress; treating chronic inflammatory bowel disorder; treating infectious diseases; and strengthening the immune system.

Tangsen et al. disclose palatinitol ingestion which shows that the absorption rate is low, most metabolites are utilized and fermented by microorganisms in the intestines to produce small molecular organic acids, CH₄, CO₂, H₂, and so on, which are discharged outside the body. Thus, Tangsen discloses administering palatinitol which acts as prebiotic. Prebiotics are known to be selectively fermented ingredients that allow specific changes, both in composition and/or activity in the gastrointestinal microflora that confers benefits upon the hosts well-being and health. Tangsen notes that palatinitol can be used to treat diseases such as hepatic coma and so on (see top of page 4). Tangsen states that there are palatinitol-containing foods on the market, such as candies, chocolates, kernel soft candies, chewing gums, ice creams, jellies, jams, etc. It is noted that the mixture applicants are seen to be using, as evidenced by claim 53, is isomalt. Isomalt is the same product as palatinitol (see section 1.2 on page 2 which provides palatinitol is a mixture

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of 1,6-GPS and 1,1-GPM). What is not taught is to add the additional agents such as Lactobacillus and Bifidobacterium.

The '784 patent bridge the gap in teaching to add various micro-organisms to prebiotic/probiotic compositions, such as Lactobacillus and Bifidobacterium. See abstract.

It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held prima facie obvious). In the instant case, Tangsen discloses administering palatinitol which acts as prebiotic. '784 teaches to add various micro-organisms to prebiotic/probiotic compositions, such as Lactobacillus and Bifidobacterium. Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the art recognized agents, to form a new composition which will be used for the very same purpose with these references before them. One would have been motivated to combine these agents to form a new composition which would be used for the very same purpose.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRAVISS C. MCINTOSH III whose telephone number is (571)272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Traviss C McIntosh III/
Primary Examiner, Art Unit 1623
June 8, 2010